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QUEEN THOMAS

Printed Name

Queen Thomas

Signature

**PATENT APPLICATION**  
**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicants : Robert Jason Herr, et al. )  
 )  
For : Compounds, Methods and Formulations for )  
the Oral Delivery of a Glucagon-Like Peptide )  
(GLP)-1 Compound or A Melanocortin-4 )  
Receptor (MC4) Agonist Peptide )  
 )  
Docket No. : X-16292 )

**INFORMATION DISCLOSURE STATEMENT**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

As a means of complying with the duty of disclosure, Applicants submit an "Information Disclosure Citation In An Application" on a Form PTO-1449 (modified) and provide a copy of each of the listed documents for consideration by the Examiner.

Since this Statement is being filed in accordance with 37 C.F.R. 1.97(b), Applicants submit that no additional fee is required.

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**10/566342**

Applicants request consideration of this information.

Respectfully submitted,

*Paula K. Davis*

Paula K. Davis  
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Registration No. 47,517  
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18-January-2006

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|--|--|--------------------------------|
| FORM PTO 1449 (modified)<br><br>INFORMATION DISCLOSURE CITATION<br>IN AN APPLICATION | Atty. Docket No.<br>X-16292                  | Serial No<br><b>10/ 566342</b> |
|  | First Applicant<br>Robert Jason Herr, et al. |                                |
|  | Filing Date                                  | Group                          |

**U.S. PATENT DOCUMENTS**

| Examiner<br>Initials* | Cite<br>No. <sup>1</sup> | Document Number                          | Publication Date<br>MM-DD-YYYY | Name of Patentee or<br>Applicant of Cited Document | Pages, Columns, Lines,<br>Where Relevant Pages<br>or Relevant Figures<br>Appear |
|-----------------------|--------------------------|--|--------------------------------|--|---|
|                       |                          | Number-Kind Code <sup>2</sup> (if known) |                                |  |   |
| /K.B./                | AA                       | US 3,578,671                             | 05-11-1971                     | Wyeth & Bros. Ltd.                                 |   |
|                       | AB                       | US 4,239,754                             | 12-16-1980                     | Sache, et al.                                      |   |
|                       | AC                       | US 4,925,673                             | 05-15-1990                     | Steiner, et al.                                    |   |
|                       | AD                       | US 5,965,121                             | 10-12-1999                     | Ho Koc-Kan et al.                                  |   |
|                       | AE                       | US 5,541,155                             | 07-30-1996                     | Leone-Bay, et al.                                  |   |
|                       | AF                       | US 5,693,338                             | 12-02-1997                     | Milstein, S.                                       |   |
|                       | AG                       | US 5,976,569                             | 11-02-1999                     | Milstein, S.                                       |   |
|                       | AH                       | US 5,643,957                             | 07-01-1997                     | Leone-Bay, et al.                                  |   |
|                       | AI                       | US 5,650,386                             | 07-22-1997                     | Leone-Bay, et al.                                  |   |
|                       | AJ                       | US 5,820,881                             | 10-13-1998                     | Milstein, S.                                       |   |
|                       | AK                       | US 5,866,536                             | 02-02-1999                     | Leone-Bay, et al.                                  |   |
|                       | AL                       | US 5,955,503                             | 09-21-1999                     | Leone-Bay, et al.                                  |   |
|                       | AM                       | US 5,965,121                             | 10-12-1999                     | Leone-Bay, et al.                                  |   |
|                       | AN                       | US 5,989,539                             | 11-23-1999                     | Leone-Bay, et al.                                  |   |

|                       |                   |                 |            |
|-----------------------|-------------------|-----------------|------------|
| Examiner<br>Signature | /Kristin Bianchi/ | Date Considered | 09/19/2008 |
|-----------------------|-------------------|-----------------|------------|

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached.

Burden Hours Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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|        |    |              |            |                   |  |
|--------|----|--------------|------------|-------------------|--|
| /K.B./ | AO | US 6,001,347 | 12-14-1999 | Leone-Bay, et al. |  |
|        | AP | US 6,071,510 | 06-06-2000 | Leone-Bay, et al. |  |
|        | AQ | US 6,100,298 | 08-08-2000 | Leone-Bay, et al. |  |
|        | AR | US 6,242,495 | 06-05-2001 | Leone-Bay, et al. |  |

**FOREIGN PATENT DOCUMENTS**

| Examiner<br>Initials* | Cite<br>No. <sup>1</sup> | Foreign Patent Document   | Publication Date<br>MM-DD-YYYY | Name of Patentee or<br>Applicant of Cited<br>Document | Pages, Columns, Lines, Where<br>Relevant Passages or Relevant<br>Figures Appear | T <sup>6</sup> |
|-----------------------|--------------------------|---|--------------------------------|---|---|----------------|
|                       |                          | Country Code <sup>3</sup> -Number <sup>4</sup> -<br>Kind Code <sup>5</sup> (if known) |                                |   |   |                |
|                       | BA                       | WO 00/40203   | 07-13-2000                     |   |   |                |
|                       | BB                       | WO 00/47188   | 08-17-2000                     |   |   |                |
|                       | BC                       | WO 00/50386   | 08-31-2000                     |   |   |                |
|                       | BD                       | WO 00/59863   | 10-12-2000                     |   |   |                |
|                       | BE                       | WO 01/32130   | 05-10-2001                     |   |   |                |
|                       | BF                       | WO 01/44199   | 06-21-2001                     |   |   |                |
|                       | BG                       | WO 01/51454   | 07-19-2001                     |   |   |                |
|                       | BH                       | WO 02/02509   | 01-10-2002                     |   |   |                |
|                       | BI                       | WO 03/072195  | 09-04-2003                     |   |   |                |
|                       | BJ                       | WO 05/000339  | 01-06-2005                     |   |   |                |

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| Examiner<br>Signature | /Kristin Bianchi/ | Date Considered | 09/19/2008 |
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|  | First Applicant<br>Robert Jason Herr, et al. |                                |
|  | Filing Date                                  | Group                          |

| NON PATENT LITERATURE DOCUMENTS |                          |  |                |
|---------------------------------|--------------------------|--|----------------|
| Examiner<br>Initials*           | Cite<br>No. <sup>1</sup> | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s) publisher, city and/or country where published. | T <sup>6</sup> |
| /K.B./                          | CA                       | DAI, Y. et al. "A Novel Series of Histone Deacetylase Inhibitors Incorporating Hetero Aromatic Ring Systems as Connection Units." Science Direct, Bioorganic and Medicinal Chemistry Letters 13, pp. 3817-3820, 2003.  |                |
| /K.B./                          | CB                       | PATEL, H. et al. "Oral Administration of Insulin By Encapsulation Within Liposomes." FEBS LETTERS, Vol. 62, No. 1, pp. 60-63, 1976.  |                |
| /K.B./                          | CC                       | HASHIMOTO, A. et al. "Effects of Oral Administration of Positively Charged Insulin Liposomes on Alloxan Diabetic Rats: Preliminary Study." Endocrinology Japan, Vol. 26, No. 3, pp. 337-344, 1979.   |                |

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|-----------------------|-------------------|-----------------|------------|
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